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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/698,858 | 10/31/2003 | Gary T. Seim | GUID.014US01(01-014) | 9341 |

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| EXAMINER | |
|---|---|
| SMITH, TERRI L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3762 | |

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/698,858 | SEIM ET AL. | |
| | Examiner | Art Unit | |
| | Terri L. Smith | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *31 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10-31-03,02-02-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 105, energy delivery circuitry (page 20, line 2). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office Action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the Applicant will be notified and informed of any required corrective action in the next Office Action. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 36–60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 36, the phrase "coupled to memory" is inferentially included and vague. It is unclear if the memory is being positively recited or functionally recited. To positively claim element, it is suggested to first positively recite the element. Otherwise functional language such as "for" or "adapted to be" should be used. Additionally, the phrase "the control system

disabling atrial ATP therapy" is likewise inferentially included and vague. It is unknown which element provides the atrial ATP therapy.

In claims 37–39, the phrases "the impedance threshold ... lead impedance measurement" are vague. It is unclear what element is performing this function in each claim.

In claims 40–41, the phrases "the impedance threshold ... measured impedance" are vague. It is unclear what element is performing this function in each claim.

In claims 46–48, the phrases "the predetermined factor ... the impedance threshold" are vague. It is unclear what element is performing this function in each claim.

In claim 49, the phrase "a pace pulse" is inferentially included and vague. It is unclear what element is providing a pace pulse.

In claim 50, the phrase "a stimulus delivered" is inferentially included and vague. It is unclear what element is providing a stimulus.

In claim 51, the phrase "after detection of an atrial arrhythmic event" is vague. It is unclear what element is providing detection of an atrial arrhythmic event.

In claim 52, the phrase "after an atrial arrhythmic episode" is vague. It is unclear what element is providing an atrial arrhythmic episode.

In claim 53, after detection of an atrial arrhythmic event" is vague. It is unclear what element is providing detection of an atrial arrhythmic event.

In claim 54, the phrase "after an atrial arrhythmic episode" is vague. It is unclear what element is providing an atrial arrhythmic episode.

Claim 60 recites the limitations "the capture threshold and sense amplitude." There is insufficient antecedent basis for these limitations in the claim.

*Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1–3, 10–19, 20, 24–27, 36–39, 44–55, and 59–62 are rejected under 35 U.S.C. 102(e) as being anticipated by Levine et al., U.S. Patent 7,031,773.

6. Regarding claims 1, 20, 36, 55, 61, and 62, (NOTE: Only the differing limitation of each claim will be indicated parenthetically; the common limitations will not be.) Levine et al. disclose measuring an impedance of an atrial lead (column 11, lines 5 and 7–10; column 13, lines 52–53; column 14, lines 21–23); comparing a measured impedance with an impedance threshold developed for a particular patient (column 11, lines 11–15; column 8, last line–column 9, lines 1–2; column 13, lines 59–60); disabling atrial ATP therapy delivery in response to a measured impedance deviating from an impedance threshold by a predetermined factor (column 11, lines 11–19 wherein the step of switching the electrode configuration to an electrode configuration other than the current electrode configuration represents disabling atrial ATP therapy delivery to the electrode configuration previously receiving the therapy); measuring a capture threshold (column 12, lines 26–28), and a sense amplitude (evoked response) (column 7, lines 59 and 65; column 10, lines 12–13 and 28–30) (claims 20, 55, and 62); comparing capture threshold, and sense amplitude measurements with capture threshold, and sense amplitude limits, respectively (column 10, lines 35–55) (claims 20, 55, and 62); an implantable housing (Fig. 1); detection

circuitry (Fig. 2); energy delivery circuitry (Fig. 2); a lead system respectively coupled to a detection and energy delivery circuitry, a lead system comprising at least an atrial lead (Figs. 1–2) and a control system provided in a housing and coupled to memory within which an impedance threshold developed for a particular patient is stored (Fig. 2) (claim 36).

7. Levine et al. disclose an impedance threshold is developed from a single atrial lead impedance measurement (claims 2, 26, and 37) and a plurality of atrial lead impedance measurements (claims 3, 27 and 38) (Fig. 3; column 11, lines 11–15); wherein measuring an impedance of an atrial lead comprises taking a plurality of impedance measurements to characterize an impedance of an atrial lead (claims 9 and 44) (Fig. 3, elements 208 and 220); measuring an impedance of an atrial lead comprises taking a single impedance measurement to characterize an impedance of an atrial lead (claims 10 and 45) (column 13, lines 52–53); a predetermined factor is characterized by a percentage change in a measured impedance relative to an impedance threshold (claims 11 and 46) (column 11, lines 10–15) and a fixed delta change (500 ohms) in the measured impedance relative to the impedance threshold (claims 12 and 47) (column 11, lines 13–14) and both a percentage change and a fixed delta change in the measured impedance relative to the impedance threshold (claims 13 and 48) (column 11, lines 10–15 and 13–14); measuring an impedance comprises delivering a pace pulse via an atrial lead and deriving an impedance measurement using a delivered pace pulse (claims 14 and 49) (Fig. 3; column 12, lines 7–14) and using a delivered stimulus, a stimulus having an energy insufficient to effect atrial capture (claims 15 and 50) (Fig. 3; column 12, lines 22–30); an impedance is measured after detection of an atrial arrhythmic event and prior to atrial ATP therapy delivery (claims 16 and 51) (Fig. 3; column 12, lines 9–25); an impedance is measured after an atrial

arrhythmic episode is declared and prior to atrial ATP therapy delivery (claims 17 and 52) (Fig. 3; column 12, lines 31–37); measuring an impedance comprises taking a plurality of impedance measurements after detection of an atrial arrhythmic event (claims 18 and 53) and after an atrial arrhythmic episode is declared (claims 19 and 54) and prior to atrial ATP therapy delivery (Fig. 3; column 12, lines 9–25); disabling ATP therapy delivery comprises, upon detection of an atrial arrhythmia, ignoring a capture threshold and sense amplitude deviations (claims 25 and 60), and disabling ATP therapy in response only to the measured impedance deviating from the impedance limit by the predetermined factor (claims 24, 25, 59, and 60) (Fig. 3; column 12, lines 31–37); an impedance threshold is capable of being characterized by a mean or a median of a plurality of atrial lead impedance measurements (claim 39) because a variance from a previous measurement by some other suitable value (as shown in column 12 lines 18–21), for example, a mean or median value, is commonly used in an impedance measurement system to measure lead impedance.

### *Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 4–8, 21–23, 28–29, 40–43, and 56–58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al., U.S. Patent 7,031,773.

Levine et al. disclose the essential features of the claimed invention as discussed above except for an impedance threshold is characterized by a mean or a median of a plurality of atrial lead impedance measurements (claims 4 and 39) and by an atrial lead impedance measurement taken immediately before a currently measured impedance (claims 5, 28 and 40) and at least one atrial lead impedance measurement taken a predetermined amount of time prior to the impedance measurement (claims 6, 29, and 41); and a predetermined amount of time is about one day (claims 7 and 42) and more than one day (claims 8 and 42). However, it is well known in the art to characterize an impedance threshold as set forth in the claim limitations stated herein because they indicate relative displacement of the implanted cardiac lead giving the physician viable information to initiate definitive therapy at the appropriate time. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Levine et al. to include an impedance threshold is characterized by a mean or a median of a plurality of atrial lead impedance measurements and by an atrial lead impedance measurement taken immediately before a currently measured impedance and at least one atrial lead impedance measurement taken a predetermined amount of time prior to the impedance measurement; and a predetermined amount of time is about one day and more than one day to provide a device that allows for delivery of optimal and efficient therapy in a timely manner.

Regarding claims 21–23 and 56–58, Levine et al. disclose the claimed invention as discussed in claims 20 and 24–25 above but does not disclose expressly detecting an ambiguity in the impedance, capture threshold, and sense amplitude deviations. It would have been an obvious matter of engineering design choice to one of ordinary skill in the art at the time the invention was made to modify the impedance, capture threshold, and sense amplitude as taught by Levine et al. (as discussed in the rejection for claims 20 and 24–25 above), to detect an ambiguity, because Applicant has not disclosed that detecting an ambiguity provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the impedance, capture threshold, and sense amplitude as taught by Levine et al., because they indicate relative displacement of the implanted cardiac lead giving the physician viable information to initiate definitive therapy at the appropriate time and provide a device that allows for delivery of optimal and efficient therapy in a timely manner.

Therefore, it would have been an obvious matter of engineering design choice to modify the impedance, capture threshold, and sense amplitude to obtain the invention as specified in the claims.

***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TLS
July 7, 2006

7 July 2006

GEORGE R. EVANISKO
PRIMARY EXAMINER
7/10/6